

PATENT
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application Number : 08/944,234 Confirmation No.: 1173
Applicant : Vincent Bryan *et al.*
Filed : October 6, 1997
Title : DRILL HEAD FOR USE IN PLACING AN INTERVERTEBRAL
DISC DEVICE
TC/Art Unit : 3727
Examiner: : Lien M. Ngo

Docket No. : 64118.44
Customer No. : 21967

DECLARATION OF CARLOS GIL

I, Carlos Gil, hereby declare and state as follows:

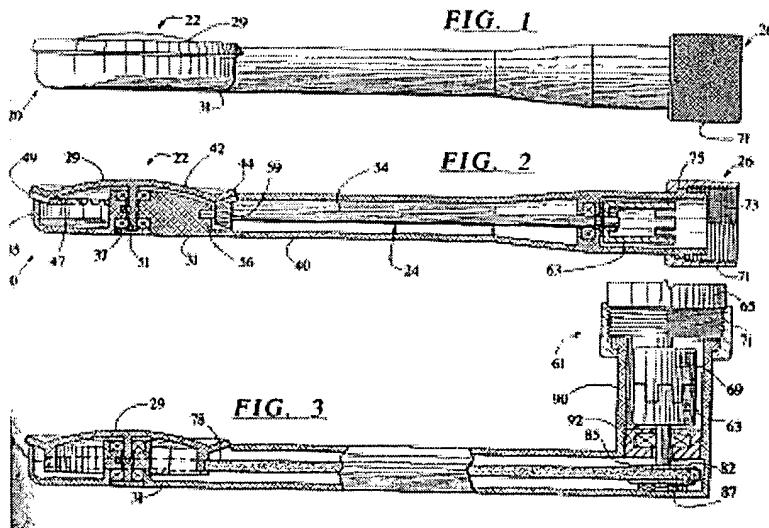
1. I am a citizen of the United States residing at 1707 Powell Run Cove, Collierville, TN 38017.
2. My educational background includes a Bachelor of Science in Engineering Technology in 1986 from the University of Memphis, located in Memphis, Tennessee, and an Associate of Science in Mechanical Engineering in 1982 from the State Technical Institute located in Memphis, Tennessee.
3. I have been in the medical orthopedic industry for 17 years. Most of my work has been in the development of orthopedic implants and associated instruments for use in hip, knee, shoulder, spine, foot, and finger surgery. The vertebral body milling apparatus which is disclosed and claimed in the application identified in caption is precisely the type of device that I have worked with and developed for most of my professional career.
4. Since 1999, I have served as Director of Product Development for Medtronic Sofamor Danek, a Delaware corporation located at 1800 Pyramid Place, Memphis, Tennessee

38132 ("Medtronic"). Medtronic is a subsidiary of SDGI Holdings, Inc. ("SDGI"), a Delaware corporation located at 300 Delaware Avenue, Suite 508, Wilmington, DE 19801. SDGI is the assignee of the present patent application, Serial No. 08/944,234.

5. I have reviewed the present application in its entirety and I am familiar with its teachings. I consider myself to be a person having at least ordinary skill in this art, and I am qualified to opine as to how a person of ordinary skill in the art would read and understand prior art to the present application.

6. The present application discloses and claims a "drill head for preparing the bone of two vertebral bodies to accept the concaval-convex shape of an endoprosthesis." *See, Abstract.* The claimed device includes a form cutter having at least one predetermined milling surface, a drive mechanism, and a housing. *Id.* The form cutter has a profile that allows the drill head to fit in the narrow space between two opposing vertebral bodies in the cervical spine of a patient. *Id.*

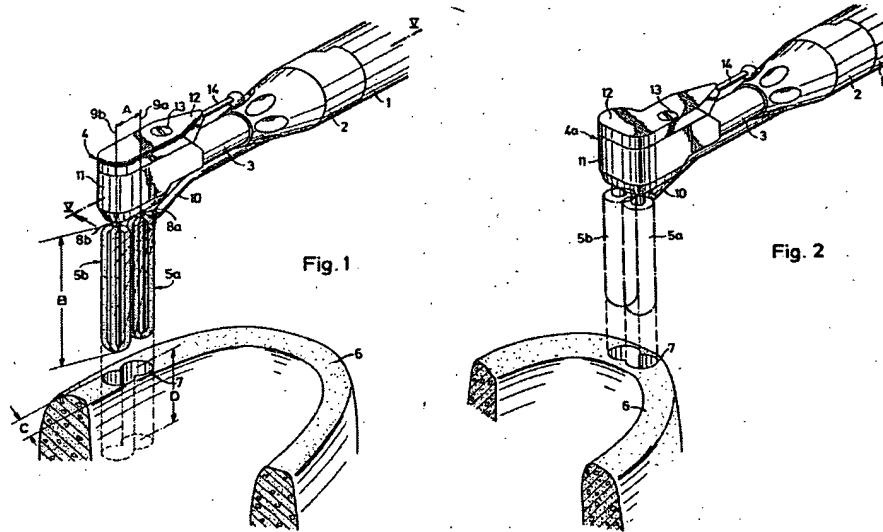
7. Figures 1-3 of the '234 application are reproduced as follows:

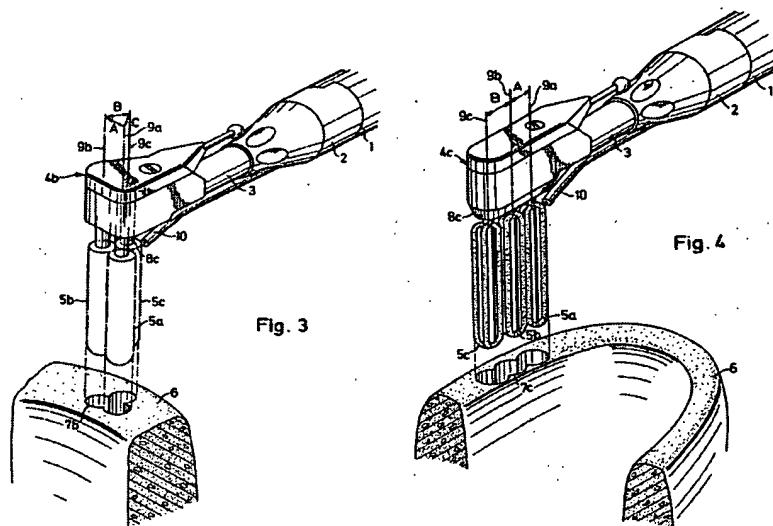


entitled "Drill Head and Bone Drill," and issued to Scheicher in 1980 (the "Scheicher patent"). The specific rejections are contained in an August 22, 2003 Final Office Action, which I have read in its entirety. I also have read the Scheicher patent in its entirety and am familiar with the devices disclosed and claimed therein.

9. The Scheicher patent, in contrast to the present application, relates to "a drilling apparatus for the preparation of bone cavities." *See Abstract of Scheicher patent.* The various embodiments disclosed in the Scheicher patent include dental drills having elongated drill bits that serve to drill teeth by positioning the drill head and drive mechanism perpendicular to the teeth. *See Figures 1-4 of the Scheicher Patent.*

10. Scheicher patent Figures 1-4 are reproduced as follows:





11. Based on my years of experience in developing and testing vertebral body milling apparatus and methods of the type disclosed and claimed in the present application, none of the devices disclosed in the Scheicher patent, including those shown above in Figures 1-4, contains all of the structural limitations of the present claims. For example, none of the Scheicher devices includes:

1. a form cutter "capable of imparting a shape to the bone of vertebral bodies which mates with the predetermined surface shape ... wherein the profile of the form cutter is of a height capable of being admitted into the space between two opposing vertebral bodies" (*See Claim 1*);
2. "wherein the rotary form cutter cuts an imparted shape to the surfaces of the vertebral bodies that matches the predetermined shape of the endoprosthesis by rotation of the rotary form cutter" (*See Claim 18*);
3. "said form cutter has at least one milling surface selected to create a surface contour in one of the adjacent vertebral bodies" (*See Claim 25*);

4. at least one milling surface “to create at least one surface having a predetermined contour in an end plate of at least one of the adjacent vertebral bodies” (*See Claim 41*);
5. “said form cutter has at least one milling surface selected to remove bone from and create a predetermined surface contour in at least one of the end plates of the adjacent vertebral bodies” (*See Claim 47*);
6. “said milling surface has a profile which mates with the profile of the insert to be implanted” and “a configuration adapted to remove bone from the vertebral bodies to prepare the vertebral bodies to receive the insert” (*See Claim 49*);
7. “said form cutter having at least one milling surface selected to create a predetermined surface contour in one of the adjacent vertebral bodies as said form cutter is moved by said drive means” (*See Claim 67*);
8. “said form cutter has at least one milling surface selected to create a predetermined surface contour in one of the adjacent vertebral bodies” (*See Claim 82*);
9. “said form cutter has at least one milling surface selected to create a predetermined surface contour in one of the adjacent vertebral bodies” (*See Claim 97*);
10. “at least one milling surface to create at least one surface having a predetermined contour in an end plate of at least one of the adjacent vertebral bodies” (*See Claim 114*);
11. “said form cutter having a broad milling surface selected to remove bone from and create a predetermined surface contour in at least one of the end plates of the adjacent vertebral bodies” (*See Claim 120*); and
12. “said at least one top milling surface of said moving form cutter being capable of removing bone from an end plate of at least one of said adjacent vertebral bodies to

create at least one surface in said end plate having a predetermined contour" (See Claim 121).

12. In addition, none of the devices disclosed in the Scheicher patent could be used to perform like the devices disclosed and claimed in the present application. For example, the devices disclosed in the Scheicher patent could not achieve the stated objective of the present application, namely the development of an apparatus that could be used to drill in-between adjacent vertebral bodies. Indeed, given the sensitive nature of the human spine, it is *impossible* to use the devices described in the Scheicher patent, or any dentist drill for that matter, to achieve the apparatus structure and functionality disclosed and claimed in the present application.

13. The August 22, 2003 Final Office Action does not expressly describe how any of the Scheicher devices include the claim recitations (1)-(12) listed above in paragraph (11), nor could the Examiner provide an explanation as to how the devices could be used during a personal interview that I attended on March 23, 2004. I note only two potential interpretations of how the devices described in the Scheicher patent might be used to, for example, meet the claim recitations set forth in (1)-(12) listed above, for example, to have a surface that removes bone in an adjacent vertebral body to create at least one surface having a predetermined contour. In one interpretation, the drill bit of the Scheicher dental drill (shown as 5a in Figure 1, for example) enters the area between two adjacent vertebral bodies in perpendicular fashion — in other words, exactly as shown in Scheicher Figure 1. In a second interpretation, the drill bit enters in parallel relation to the vertebral surfaces; that is, the length of drill bit 5a would be parallel to the surfaces of the vertebral bodies. Notably, neither approach provides a cutting surface as

described and claimed in the present application. Indeed, any effort to do so would expose a patient to life-altering and or life-threatening injuries.

14. Inserting any of the Scheicher device drill bits perpendicularly into a space between two vertebral bodies — essentially as shown in Scheicher Figures 1-4 shown above — would not work given the narrowness of that space. The inventors of the present application state in the specification that the distance between adjacent vertebral bodies is approximately nine millimeters. *See*, ‘234 Application. The Scheicher patent, on the other hand, states — and the Final Office Action notes — that the distance between the various drill bits “lie in a region of about 2.5 mm to about 10 mm, preferably about 2.8 mm to about 6 mm, if the drill head is used in the dental region.” *See* Col. 17, lines 51-58. Given this, it is clear that the distance B shown in Fig. 1 of the Scheicher patent, for example, far exceeds nine millimeters, making a perpendicular insertion into the space between two adjacent vertebral bodies impossible to achieve. Accordingly, one could not even enter the inter-vertebral space, let alone cut a shape into an adjacent vertebra corresponding to the shape that Scheicher seeks to obtain for its implant in Figures 1-4.

15. The other interpretation, (*i.e.*, providing the drill bits of the Scheicher patent parallel to a surface a vertebral body), fares no better. In essence, while using this approach might permit insertion of the drill bit in the inter-vertebral space, the Scheicher device does not provide, as is required by the present claims, a surface that creates a surface contour in an adjacent vertebral body, and certainly could not be used to create at least one surface having a predetermined contour in an end plate of at least one adjacent vertebral body. When placed on the surface of a vertebral body, the tendency of the Scheicher device’s drill head would be to roll off, much like a wheel does when coming in contact with a hard, solid surface. This lack of

control essentially renders the Scheicher device a useless (and potentially life threatening) instrumentality for performing the type of spinal surgery contemplated by the claimed invention. More importantly, such lack of control means that the Scheicher device does not provide, as does the claimed invention, a surface that removes bone and creates a predetermined surface adapted to receive a prosthetic.

16. In view of the above statements, it is my opinion that the device disclosed by Scheicher does not provide a milling surface enabling the formation of a predetermined shape on an adjacent vertebral body, as does the device according to the present invention.

17. I further declare that all statements made herein are based on personal knowledge or upon information and belief and are believed to be true; and further that the statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above-identified application or any patent issuing thereon.

CARLOS GIL



Carlos Gil
Director of Product Development
Medtronic Sofamor Danek

Dated: April 22, 2004